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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,824	11/14/2003	Alan E. Nash	3282/30US	2581

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
11/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,824	NASH, ALAN E.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *9-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant' amendment filed 08/31/2007.

Claims 1-8 have been pending, claims 9-15 have been added.

Claims 1-15 are pending.

Election/Restrictions

1. Newly submitted claims 9-15 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly added claims are directed to two inventions that are distinct from the invention of claims 1-8. The product of claims 9-14 and the method of claim 15 do not require PM and AM treatment, additionally, the newly added product and method require trimming of the medicated patches that is not required by invention 1-8. Furthermore, the invention of claims 9-14 requires that medicated patch comprises non-woven material that not required by any of claims 1-8 or claim 15.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 9-15 are withdrawn from consideration

as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-8 are included in the prosecution.

The following rejections/objections have been overcome by virtue of applicant's amendment and remarks:

(A) The objection made to the abstract and to the specification.

(B) The rejection of claims 1-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

(C) The rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following rejection has been discussed in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0013300 (300) in view of US 6,303,140 ('140) or vise versa, and further combined teachings of US '300 and US '140 in view of US 2005/0042267 ('267).

The present claims are directed to box comprising multiple patches some contain salicylic acid and some are not.

US '300 teaches kit in a package for treating scar wherein the kit comprising composition comprising salicylic acid to be applied topically to the skin and thermal insulating material to cover the area of the skin after contacted the skin with the composition to elevate the scar temperature and bring about improvement in the size of the scar (paragraphs 0019, 0058, 0059, 0062, 0063, 0111). The thermal insulating material can be a sponge made of collagen, which reads on the medicated hydrocolloid patch and also reads on foam cover (paragraphs 0064, 0076, 0086, 0087). The reference teaches using various hydrogel combinations in sequence that suggests AM and PM patches (0088).

The difference between the present claims and US '300 is that US '300 does not teach the composition comprising the salicylic acid in the form of a patch and does not teach the amount of salicylic acid as instantly claimed.

US '140 teaches a medicated plaster comprises salicylic acid in amount preferably from 36-44% (abstract; col.3, lines 25-32). The plaster has advantage of efficaciously release the active agent into the skin at a sufficient rate and/or quantity to treat or remove corns and calluses (col.1, lines 45-48). The medicated plaster is applied according to a regimen effective to remove corns or calluses and typically the

medicated plaster is covered with an enclosed cushion or pad (col.5, lines 4-14). The medicated plaster is further attached to a substrate to provide occlusive properties and dimensional strength to the plaster, i.e. backing (col.4, lines 33-38).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide sequence of treatment comprising applying topical composition comprising salicylic acid to the skin then cover it with hydrogel sponge as disclosed by US '300, and replace the topical composition with a medicated plaster comprising 36-44% salicylic acid as disclosed by US '140, motivated by the teaching of US '140 that application of that amount of salicylic acid in a medicated plaster has advantage of efficaciously release the active agent into the skin at a sufficient rate and/or quantity to treat or remove corns and calluses, with reasonable expectation of treating corns or calluses using medicated plaster that efficaciously release the active agent into the skin at a sufficient rate and/or quantity and covered with hydrogel sponge. In addition one having ordinary skill in the art would have added substrate to the hydrogel disclosed by US '300 as disclosed by US '140, motivated by the teaching of US '140 that the substrate provides occlusive properties and dimensional strength to the plaster, with reasonable expectation of having patches of sponge hydrogel having substrate with sufficient strength and occlusive properties to cover the medicated patches of salicylic acid.

Vise versa, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medicated plaster comprises salicylic acid in amount preferably from 36-44% covered with cushion or pad as disclosed by US '140, and

apply a hydrogel sponge after the application of salicylic acid as disclosed by US '300, motivated by the teaching of US '300 that such a hydrocolloid hydrogel elevates the skin temperature underneath it and brings about improvement in the size of the scar, with reasonable expectation of having skin treatment comprising applying salicylic acid patch covered with a cushion or pad followed by application of hydrocolloid hydrogel sponge to elevate the temperature of the skin underneath the sponge with the benefit of improving the underlying skin condition.

The combination of US '300 and US '140 does not teach the kit comprises plurality of patches.

US '267 teaches system comprising plurality of patches that provide different types of therapy are packaged together in one container, and plurality of patches are held by one carrier (abstract; figures 3 and 5; paragraphs 0011, 0013, 0029, 0033, 0041). The system makes it easier for the user or therapist to readily choose an appropriate therapy (paragraph 0012).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide treatment kit comprising patches comprising salicylic acid, protective cushions or pads, and patches to cover the salicylic acid patches as disclosed by the combined teachings of US '300 and US '140, and package all the patches in one container as disclosed by US '267, motivated by the teaching of US '267 that such a system packaging plurality of patches having different materials makes it easier for the user or therapist to readily choose an appropriate therapy, with reasonable expectation of having package comprising patches containing salicylic acid

covering pads, and hydrogel sponges all in one container with the benefit of easiness for the user or therapist to readily choose an appropriate therapy.

Response to Arguments

4. Applicant's arguments filed 08/31/2007 have been fully considered but they are not persuasive.

Applicant traverse this rejection by arguing that the collagen disclosed by US '300 is not a hydrocolloid.

Applicant further argues that claims 9-15 are allowable because they recite trimming the medicated patch which limitation is not disclosed by the cited prior art.

In response to applicant argument regarding the nature of collagen , it is argued that collagen can be provided in the hydrocolloid form as evident by the teaching of US 4,728,642, col.9, lines 29-35, wherein collagen is taught as hydrocolloid. Therefore, the combination of the prior art teaches the present invention as whole. It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Regarding claims 9-15, the claims have been withdrawn from consideration as being directed to two distinct inventions: product and process of use that requires trimming of the medicated patch as set forth in section 1 of this office action.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2004/0202706 teaches kit comprising topical composition including salicylic acid and hydrogel patches to occlude the composition.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
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ISIS GHALI
PRIMARY EXAMINER